UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. CUSTOM ULTRASONICS, INC., a corporation, and FRANK J. WEBER, an individual, Defendants.	)	NO. 06-5267 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by Patrick L. Meehan, United States Attorney for the Eastern District of Pennsylvania, having filed a complaint for permanent injunctive relief against Custom Ultrasonics, Inc. ("CUI"), a corporation, and Frank J. Weber, an individual (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, before any testimony has been taken, without adjudication of any issue of fact or law and without Defendants admitting liability for any of the violations alleged in the Complaint, and the United States having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to

this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345. Venue is proper in this District under 28 U.S.C. §§ 1391(b)and(c).

2. The Complaint for Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. Upon entry of this Decree, Defendants and each of their officers, directors, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are enjoined from manufacturing, packing, labeling, and distributing any device (including components and systems) at and from its facility located at 144 Railroad Drive, Ivyland, Pennsylvania, and at any other location(s), unless and until Defendants:

A. Adequately and fully comply with Current Good Manufacturing Practices ("CGMP") and the Quality System Regulation ("QS Regulation") (collectively "CGMP/QS Regulation") requirements as set forth at 21 C.F.R. Part 820 including, but not limited to, the following:

1) Establish and implement adequate written procedures for corrective and preventive actions to detect and correct quality system deficiencies;

2) Establish and implement adequate written procedures to identify the action needed to correct and prevent recurring nonconforming product and other quality problems;

3) Establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints by a formally designated unit;

4) Establish and implement adequate written procedures for reviewing and evaluating all complaints to determine whether an investigation is necessary;

5) Establish and implement adequate written procedures for identifying, documenting, evaluating, segregating, and disposing product that does not meet its specifications;

6) Establish and implement adequate written procedures to control design processes of devices;

7) Establish and implement adequate written procedures for identifying, documenting, validating or verifying, reviewing, and approving design changes prior to their implementation;

8) Develop and implement adequate written procedures and methods that define and control the manner of production;

9) Establish and implement adequate written procedures for reviewing the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency according to adequately established procedures to ensure that the quality system is in compliance with CGMP/QS Regulation requirements;

10) Establish and implement adequate written procedures to conduct quality audits to ensure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system; and

11) Establish and implement adequate written procedures for identifying employee training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, including, but not limited to, employees who do not speak or understand English.

B. Defendants recall at their own expense all System 83 Plus Mini-Flex devices from any source that were sold or shipped at any time prior to the entry of this Decree.

C. Defendants develop and implement adequate written Medical Device Reporting ("MDR") procedures in compliance with 21 C.F.R. Part 803.

D. Defendants select and retain, at Defendants' expense, an independent person or persons (the "expert"), who is qualified by education, training, and experience to evaluate whether Defendants are in compliance with CGMP/QS Regulation requirements as set forth at 21 C.F.R. Part 820 and the MDR reporting requirements set forth at 21 C.F.R. Part 803, as well as the premarket notification requirements of 21 C.F.R. Part 807 Subpart E, the IDE requirements of 21 C.F.R. Part 812, and the PMA requirements of 21 C.F.R. Part 814, as applicable. The

expert(s) shall be without personal or financial ties (other than the consulting agreement between the parties) to any officer or employee of Defendants or their immediate families. Defendants shall notify the U.S. Food and Drug Administration ("FDA") in writing of the identity of the expert(s) as soon they retain such expert(s), and the expert(s) shall:

1) Determine whether Defendants are in compliance with the CGMP/QS Regulation requirements as set forth at 21 C.F.R Part 820 and the MDR requirements as set forth at 21 C.F.R. Part 803, as well as the premarket notification requirements of 21 C.F.R. Part 807 Subpart E, the IDE requirements of 21 C.F.R. Part 812, and the PMA requirements of 21 C.F.R. Part 814, as applicable; and

2) Provide FDA with a complete and adequate written evaluation of Defendants' compliance with CGMP and 21 C.F.R. Parts 820 and 803, and 21 C.F.R. Parts 807 Subpart E, 812, and 814, as applicable.

E. Defendants submit an adequate written report of all corrections Defendants have made to come into compliance with the requirements of the Act, 21 C.F.R Parts 820 and 803, and 21 C.F.R. Parts 807 Subpart E, 812, and 814, as applicable, and the terms of this Decree.

F. Defendants submit a written report to FDA documenting what steps have been taken to ensure that Defendants' employees and managers, including, but not limited to, those who do not

speak or understand English, are adequately trained in the requirements of CGMP/QS Regulation, and MDR requirements applicable to their assigned responsibilities and positions.

G. The expert(s) has certified to FDA in writing that Defendants are in compliance with the Act, CGMP, 21 C.F.R Parts 820 and 803, and 21 C.F.R. Parts 807 Subpart E, 812, and 814, as applicable, and the terms of this Decree.

H. Duly authorized FDA representatives have made inspections, as and when FDA deems necessary and without prior notice, of Defendants' facilities, including buildings, equipment, personnel, finished and unfinished materials, containers and labeling, and all records relating to the manufacturing, packing, labeling, and distributing of devices, to determine whether the requirements of paragraphs 3(A-C) of this Decree have been met; and

I. FDA notifies Defendants, in writing, that they may commence manufacturing, packing, labeling, and distributing medical devices.

4. After Defendants resume manufacturing, packing, labeling, and distributing devices pursuant to paragraph 3(H). above, Defendants and each of their officers, directors, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by

personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. violates 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce any article of device, within the meaning of 21 U.S.C. § 321(h), that is adulterated within the meaning of 21 U.S.C. §§ 351(h) or 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(o) or 352(t)(2); or

B. violates 21 U.S.C. § 331(e), by failing to comply with the requirements of 21 U.S.C. § 360i and its implementing regulations.

5. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, a sample analysis, a report or data prepared or submitted pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or any applicable regulation, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or any applicable regulation, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate action, including, but not limited to, ordering Defendants immediately to take one or more of the following actions:

A. Cease manufacturing, packing, storing, and distributing devices (including components and systems);

B. Revise, modify, or expand any reports or plans prepared pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall devices released or distributed by Defendants or under the custody and control of Defendants' agents, distributors, customers, or consumers. Defendants shall bear the costs of any such recalls; or

E. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with the Act, the applicable regulations, and the terms of this Decree.

Defendants shall immediately implement any and all measures under this paragraph as directed by FDA.

6. If any Defendant fails to comply with any of the provisions of this Decree, that Defendant shall pay to the United States of America the sum of five thousand dollars ($5,000.00) in liquidated damages for each day that Defendant is in violation of this Decree and, in addition, for each violation. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil contempt penalties

based on conduct that may also be the basis for the payment of liquidated damages.

7. Duly authorized representatives of FDA are authorized, as and when FDA deems necessary and without prior notice, to inspect Defendants' facilities and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives are authorized to inspect all equipment, finished and unfinished materials and products, containers, and labeling therein; to take photographs and make video recordings; to collect samples of any articles of device; and to examine and copy all records relating to the manufacture, packing, labeling, storage, and distribution of any of Defendants' products. Defendants shall bear the costs of all inspections, document reviews, and sample analyses at the rates specified in paragraph 8 of this Decree. These inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. Defendants shall pay the costs of FDA's supervision, inspections, examinations, reviews, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree

is signed by the parties, the rates are: $76.10 per hour or fraction thereof per representative for time spent on supervision other than laboratory and analytical work; $91.18 per hour or fraction thereof per representative for laboratory and analytical work; $0.445 per mile for travel expenses; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

9. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each of their officers, directors, agents, employees, representatives, attorneys, and any and all persons in active concert or participation with any of them. Defendants shall also post a copy of this Decree in the employee common areas at all of their manufacturing facilities. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, based upon personal knowledge of the affiant, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree. In addition, the affidavit shall state how the requirements of this Decree were

explained to any employee or manager who does not speak or understand English.

10. Defendants shall notify FDA at least fifteen (15) calendar days before change in ownership or character of their business, such as reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity, the creation or dissolution of subsidiaries, or any other change in the corporate structure of CUI, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days before any change in ownership or character of their business.

11. Defendants and Defendants' expert(s) shall address all communications with FDA required under this Decree to the Director, Philadelphia District Office, U.S. Food and Drug Administration, 900 U.S. Customhouse, 200 Chestnut Street, Philadelphia, PA 19106.

12. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States

for its attorneys' fees, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

13. Defendants shall abide by the decisions of FDA, which decisions shall be final. All decisions specified in this Decree shall be vested in the discretion of FDA, which discretion shall be reviewed, if contested, by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

14. If defendants maintain a continuous state of compliance with this Decree and the Quality System Regulation for a period of five (5) years after the date of entry of this Decree and FDA has not notified the defendants that there has been a significant violation of this Decree or the Quality System Regulation during such time, the government will not oppose the defendants' petition to the Court to dissolve this Decree.

15. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to enforce or modify this Decree and for granting such other relief as may be necessary or appropriate for the proper disposition of this proceeding.

SO ORDERED:

Dated this 25th day of January, 2007.

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree:

FOR DEFENDANTS:

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and Chief Executive Officer,
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